Patellar Resurfacing in Total Knee Replacement: Five-Year Clinical and Economic Results of a Large Randomized Controlled Trial

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Background: There is conflicting evidence regarding the merits of patellar resurfacing during total knee arthroplasty, as many of the previous randomized controlled trials have not been adequately powered.

Methods: A pragmatic, multicenter, randomized controlled trial was initiated in 1999 in the United Kingdom. Within a partial factorial design, 1715 patients were randomly allocated to receive or not receive patellar resurfacing during total knee arthroplasty. The primary outcome measure was the Oxford Knee Score; secondary measures included the Short Form-12, the EuroQoL 5D, cost, cost-effectiveness, and the need for subsequent knee surgery.

Results: The mean Oxford Knee Score was 35 points at five years postoperatively in both groups. There was no significant difference between the groups with respect to the mean Oxford Knee Score (difference, 0.59 point; 95% confidence interval, –0.58 to 1.76 points) or any other outcome measure at five years postoperatively. The outcome was not affected by whether the patella was domed or anatomic. There was no significant difference between the two groups with respect to the prevalence of knee-related readmission, of minor or intermediate reoperation, or of subsequent patella-related surgery. The total health care cost for the primary arthroplasty, subsequent monitoring, and any revision surgery did not differ significantly between the two groups.

Conclusions: In the largest randomized controlled trial of patellar resurfacing reported to date, the functional outcome, reoperation rate, and total health care cost five years after primary total knee arthroplasty were not significantly affected by the addition of patellar resurfacing to the surgical procedure.

Level of Evidence: Therapeutic Level I. See Instructions to Authors for a complete description of levels of evidence.

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Disclosure: One or more of the authors received payments or services, either directly or indirectly (i.e., via his or her institution), from a third party in support of an aspect of this work. In addition, one or more of the authors, or his or her institution, has had a financial relationship, in the thirty-six months prior to submission of this work, with an entity in the biomedical arena that could be perceived to influence or have the potential to influence what is written in this work. No author has had any other relationships, or has engaged in any other activities, that could be perceived to influence or have the potential to influence what is written in this work. The complete **Disclosures of Potential Conflicts of Interest** submitted by the authors of this work are always provided with the online version of this article at jbjs.org.

A commentary by Allan E. Gross, MD, FRCSC, O.Ont, is linked to the online version of this article at jbjs.org.

Total knee arthroplasty is a common surgical procedure. Long-term observational studies have indicated that more than 90% of modern primary total knee replacements survive for at least fifteen years[1]. However, a substantial proportion of patients have a poor functional result and persistent knee pain[2]. Many of these poor results are attributed to problems arising from the patellofemoral joint, and there is considerable debate regarding whether the patella should be resurfaced at the time of the primary total knee arthroplasty. Previous nonrandomized cohort studies, small randomized trials, and systematic reviews have not resolved the uncertainty regarding the benefits of patellar resurfacing[3-18], as many of the previous randomized controlled trials have not been adequately powered.

The Knee Arthroplasty Trial (KAT) was initiated in 1999 to assess the merits of four knee replacement options: patellar resurfacing, a metal-backed tibia, mobile bearing surfaces, and unicompartmental replacement. The study was a partial factorial, pragmatic, multicenter, randomized controlled trial designed to assess clinical outcomes, complications, and cost-effectiveness. The aim of a pragmatic trial is to estimate effectiveness rather than efficacy within routine clinical practice[19]. Full details of the KAT study and the two-year outcomes have been published previously[20]. The purpose of the present report is to present the five-year clinical outcomes, complications, and health care costs in the portion of the study that addressed whether or not the patella should be resurfaced during the primary arthroplasty procedure. To our knowledge, it is the largest randomized trial to address this issue to date.

Materials and Methods

The trial was approved by the relevant national and local research ethics committees and was registered in a public trials registry (International Standard Randomized Trial No. ISRCTN45837371). Any orthopaedic surgeon in the United Kingdom who performed knee replacements regularly was eligible to participate in the trial. One hundred and sixteen surgeons in thirty-four centers in the United Kingdom participated in the KAT study, and ninety-nine (85%) of these surgeons recruited patients to the patellar resurfacing comparison.

All patients under the care of a participating surgeon were potentially eligible for inclusion in the overall study if they were scheduled to undergo a primary total knee arthroplasty. A patient was not eligible for a particular comparison within the study if the surgeon considered only one of the two surgical procedures in that comparison to be indicated.

Suitable alternative prosthesis designs were available for each of the possible randomized choices within the study. Surgeons followed their standard practice, and the outcomes would thus not have been influenced by a so-called learning-curve effect. We did not influence surgeons regarding the choice between a cruciate-retaining and a cruciate-substituting implant. All other aspects of patient care were left to the discretion of the responsible surgeon.

The primary outcome measure was the functional status as measured with use of the Oxford Knee Score (OKS)[21], which was developed specifically to measure outcomes of knee replacement and has been shown by independent studies to perform well compared with alternative outcome instruments[22-24]. A power calculation indicated that 1400 participants would provide 80% power to detect a 1.5-point difference in the OKS (two-tailed $p < 0.05$). Secondary outcome measures included the quality of life as measured with use of the Short Form-12 (SF-12)[25] and the EuroQoL 5D (EQ-5D)[26,27], intraoperative and postoperative complications including the need for subsequent surgery, cost, and cost-effectiveness. In addition, question 12 of the OKS was analyzed in isolation as a secondary outcome since it assesses the ability to walk downstairs, which is one aspect of knee function that patellar resurfacing may influence. The five possible responses for question 12 were "No, impossible" (scored as 0), "With extreme difficulty" (1), "With moderate difficulty (2), "With little difficulty" (3), and "Yes, easily" (4).

Patients were randomized to receive or not receive patellar resurfacing with use of computer-generated random numbers obtained via an automated, centralized telephone service. Randomization was stratified by surgeon, with minimization according to patient age (less than 60 years, 60 to 79 years, or 80 years or older), sex, and location of disease (one knee, both knees, or general arthritis). Patients were not blinded to treatment allocation.

Preoperative, operative, and postoperative data on the surgery, knee components used, length of hospital stay, operative time, and complications were collected prospectively on standard forms. This information was supplemented with routinely collected information from the Hospital Episode Statistics (HES) database in England or the Information Services Division (ISD) in Scotland if such data were available. Data describing functional status and quality of life were obtained directly from questionnaires completed by participants preoperatively, at three months after the operation, at one year, and annually thereafter. Patients who did not return the questionnaire were offered the option of completing the questionnaire over the telephone. The questionnaire included the OKS, SF-12, and EQ-5D, as well as questions regarding hospital admissions and ambulatory consultations with general practitioners, physical therapists, and hospital physicians related to the involved knee. The patient's case notes were reviewed if the questionnaire or the HES or ISD data indicated subsequent knee-related surgery or hospital readmissions, and such events were classified according to severity. The severity categories were (1) patella-related reoperation (late patellar resurfacing or surgical treatment of a patellar fracture), (2) major reoperation (revision arthroplasty or amputation), (3) minor or intermediate reoperation (an operation with a degree of severity between that of wound closure and that of manipulation under anesthesia, or an operation due to arthrofibrosis), and (4) readmission or other subsequent intervention (any readmission or any intervention such as an injection).

List prices for knee components were obtained from manufacturers; a 30% discount was applied to list prices to reflect the price likely to be paid by a typical hospital, although the actual discounts would vary. Other estimated unit costs are listed in the Appendix, along with the sources from which they were derived. Unit costs and resource use data were combined to calculate the total cost per patient associated with the knee arthroplasty during the first five years. The total cost included the costs associated with the hospital stay for the primary arthroplasty and for any related readmissions, the operating room used for the primary arthroplasty and for any subsequent related surgery, the knee arthroplasty components, blood transfusions, computed tomography or ultrasonographic scans, and consultations with general practitioners, physical therapists, and outpatient physicians related to the involved knee. Cost analyses were conducted from the perspective of the health system and thus excluded any costs incurred by patients or their employers. Costs incurred after the first postoperative year were discounted at 3.5% per year[28]. Full details of the cost analysis and the results of sensitivity analyses will be reported separately.

Data were analyzed on the basis of the procedure allocation, regardless of the method of knee replacement that was actually used (i.e., analysis was performed on the basis of the intention-to-treat principle). Functional status and quality-of-life outcomes were compared with use of an analysis of covariance that adjusted for baseline scores and the minimization factors. The proportion of patients with readmissions and/or subsequent surgery was analyzed with use of logistic regression analysis; rare events were analyzed with use of the exact logistic regression command in Stata Version 11.0 (StataCorp, College Station, Texas). Descriptive statistics are presented when appropriate, and effect sizes are presented with associated 95% confidence intervals (CIs) estimated with use of robust standard errors to account for potential surgeon effects.

Since 44% (732) of the 1671 patients analyzed had missing data for at least one resource use item and some missing data (for example, length of stay for a revision procedure) were not missing completely at random, a complete case analysis of cost data would have been inefficient and prone to bias[29]. We therefore used the ICE command[30] in Stata to impute missing data regarding component prices and resources with use of multiple imputation[29,31]. Multiple imputation predicts missing values by iteratively estimating regression models based on observed and imputed data; this enabled missing data on specific resource items to be imputed on the basis of the patient's age, sex, and treatment allocation; the quantities of other resources that they required; and the correlations observed among these variables for other patients. Imputation was performed on the entire trial dataset (with the exception of patients excluded after randomization). Costs are presented as the mean and standard deviation for each group and are expressed in pounds Sterling at 2007-2008 prices (£1 = US$2 in 2007-2008). The mean difference (and 95% CI) between groups was calculated across the ten imputed datasets with use of the MICOMBINE command in Stata.

Source of Funding

The Knee Arthroplasty Trial was funded by the National Institute for Health Research (NIHR) Health Technology Assessment programme (project number 95/10/01). Additional funding for research support at the clinical centers was provided by Stryker Orthopaedics (formerly Howmedica Osteonics) (Newbury, Berkshire, United Kingdom); Zimmer (Swindon, Wiltshire, United Kingdom); DePuy, a Johnson & Johnson company (Leeds, United Kingdom); Corin Medical (Cirencester, Gloucestershire, United Kingdom); Smith & Nephew Healthcare (Cambridge, United Kingdom); Biomet Merck (Bridgend, South Wales, United Kingdom); and Wright Medical (formerly Wright Cremascoli) (Woking, Surrey, United Kingdom). Core funding for the Health Services Research Unit was provided by the Chief Scientist Office of the Scottish Government Health Directorates. The Musculoskeletal Biomedical Research Unit in Oxford was funded by the NIHR. The Health Economics Research Centre in Oxford received some core funding from NIHR.

Results

From July 1999 to January 2003, 4070 potentially eligible patients were identified and 2374 (58%) gave their consent and were randomized for treatment. Of these, 1715 patients were suitable for the comparison assessing patellar resurfacing. Forty patients were subsequently withdrawn, two died prior to surgery, and the procedure received by sixteen could not be determined (Fig. 1). Of the 1715 patients formally enrolled in the trial comparison, 1424 (83%) received the allocated procedure. Ninety-five (11.1%) of the 854 patients who were allocated to receive no resurfacing had the patella resurfaced, and 138 (16.0%) of the 861 patients who were allocated to resurfacing did not have the patella resurfaced. The most common reasons for

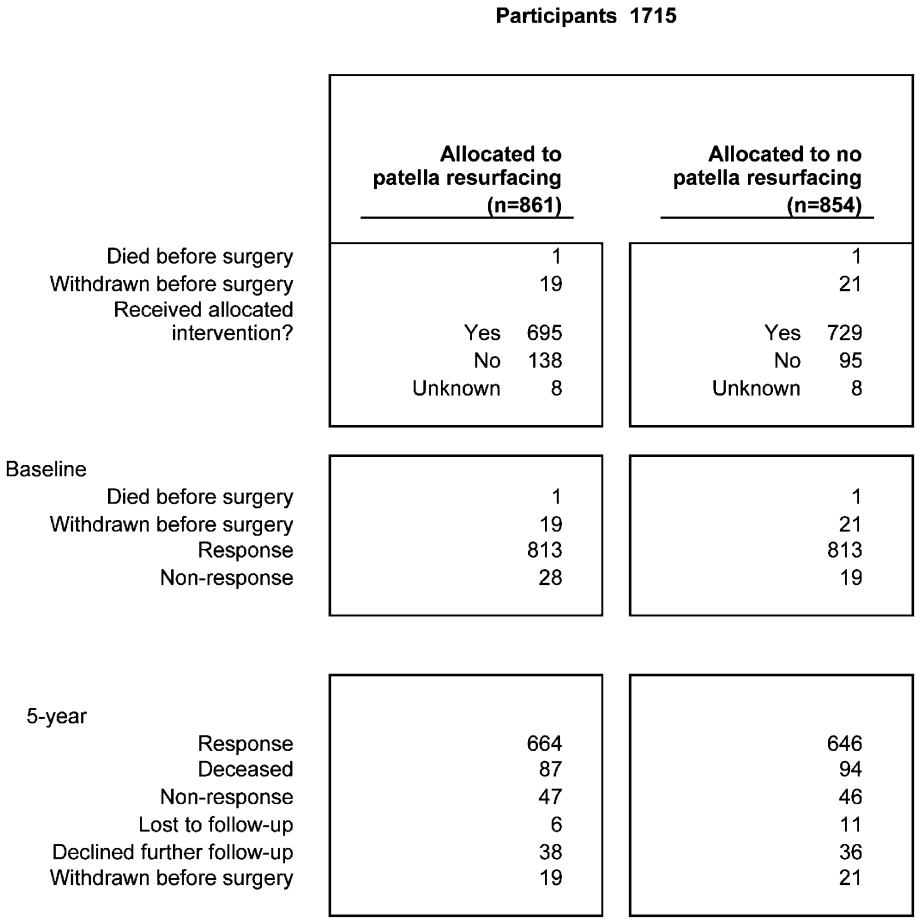

Fig. 1

CONSORT (Consolidated Standards of Reporting Trials) diagram showing the flow of patients through the trial.

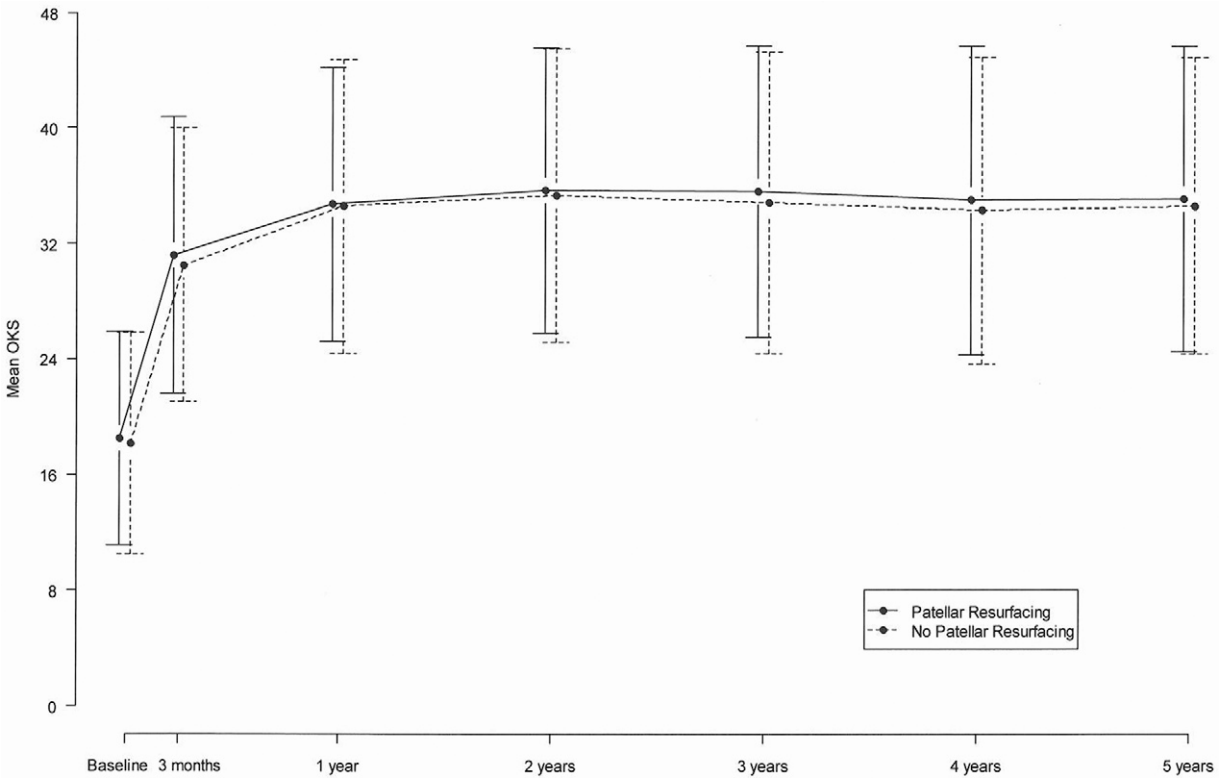

Fig. 2

Comparison of the mean Oxford Knee Score (OKS) in the group allocated to receive patella resurfacing and in the group allocated to receive no patellar resurfacing. The bars represent one standard deviation.

noncompliance were a clinical decision made at the time of the operation or a logistical constraint such as unavailability of the prostheses at the time of surgery. The two randomized groups were well matched (see Appendix), as described previously[20]. The mean age was seventy years in both groups, and the percentage of male patients was 45% in the patellar resurfacing group and 44% in the nonresurfacing group. The mean body-mass index was 30 kg/m^2 in both groups, and the percentage of patients with knee osteoarthritis was approximately 96% in both groups. The distribution of scores on the American Society of Anesthesiologists (ASA) classification system and the percentage of patients with a history of previous knee surgery were similar in the two groups.

There was no statistically significant difference between the groups either in the overall rate of short-term complications[20] or in any of the patient-assessed outcomes at baseline or at any subsequent time point (Fig. 2, Table I). The mean OKS value in both groups increased from 18 points preoperatively to 35 points at five years postoperatively. The difference in the OKS value between the groups was 0.59 point (95% CI, –0.58 to 1.76 points) at five years postoperatively. The mean EQ-5D score was 0.4 point preoperatively and 0.6 point at five years postoperatively in both groups. The mean SF-12 physical component score increased from 31 points preoperatively to approximately 39.5 points at five years postoperatively in both groups. The mean SF-12 mental component score was approximately 50 points for both groups preoperatively and at five years postoperatively. An analysis of outcomes according to the femoral component shape (whether or not the trochlear groove was appropriate for an anatomical or a domed patella) revealed no statistically significant differences. The mean score on question 12 of the OKS, which inquires about the ability to walk down stairs, was 2.21 ± 1.16 points for the patellar resurfacing group compared with 2.33 ± 1.16 points in the nonresurfacing group (difference, –0.09 point; 95% CI, –0.22 to 0.04 point; p = 0.152).

The percentage of patients who required readmission and/or further intervention was 12.1% in the patellar resurfacing group compared with 13.1% in the nonresurfacing group (odds ratio, 0.91; 95% CI, 0.67 to 1.23; p = 0.54) (Table II); 4.4% of the patellar resurfacing group and 5.8% of the nonresurfacing group required further minor or intermediate surgical procedures (odds ratio, 0.74; 95% CI, 0.44 to 1.25; p = 0.27); 1.6% of the patellar resurfacing group and 2.9% of the nonresurfacing group required further major surgical procedures (odds ratio, 0.56; 95% CI, 0.29 to 1.06; p = 0.076); and 1.0% of the patellar resurfacing group and 1.9% of the nonresurfacing group had further patella-related surgery (odds ratio, 0.55; 95% CI, 0.21 to 1.34; p = 0.22). The reasons for further knee surgery included infection, knee pain, knee stiffness, implant loosening, and knee instability. The proportion of patients requiring further surgery did not differ significantly between the patellar resurfacing and

TABLE I Patient-Assessed Outcomes at All Time Points Up to Five Years*

	Allocated to Patellar Resurfacing†	Allocated to No Patellar Resurfacing†	Difference (95% CI)‡
OKS			
Baseline	18.49 ± 7.39	18.15 ± 7.66	
3 months	31.19 ± 9.56	30.49 ± 9.45	
1 year	34.66 ± 9.44	34.53 ± 10.16	
2 years	35.61 ± 9.83	35.25 ± 10.15	
3 years	35.52 ± 10.08	34.72 ± 10.41	
4 years	34.93 ± 10.67	34.23 ± 10.59	
5 years	35.01 ± 10.55	34.57 ± 10.25	0.59 (–0.58 to 1.76)
EQ-5D			
Baseline	0.40 ± 0.30	0.39 ± 0.31	
3 months	0.70 ± 0.24	0.69 ± 0.25	
1 year	0.73 ± 0.25	0.71 ± 0.28	
2 years	0.72 ± 0.27	0.68 ± 0.31	
3 years	0.69 ± 0.30	0.65 ± 0.33	
4 years	0.65 ± 0.33	0.62 ± 0.32	
5 years	0.63 ± 0.34	0.61 ± 0.34	0.01 (–0.02 to 0.4)
SF-12 (v2) physical component			
Baseline	31.07 ± 8.05	31.26 ± 8.5	
3 months	39.42 ± 9.35	38.68 ± 9.06	
1 year	40.82 ± 10.51	40.72 ± 10.39	
2 years	40.66 ± 10.99	40.84 ± 10.39	
3 years	40.76 ± 11.09	39.86 ± 10.92	
4 years	39.74 ± 11.41	39.23 ± 10.88	
5 years	39.61 ± 11.01	39.39 ± 11.48	0.23 (–0.99 to 1.46)
SF-12 (v2) mental component			
Baseline	50.70 ± 11.37	49.73 ± 11.20	
3 months	51.21 ± 10.60	51.14 ± 10.97	
1 year	52.31 ± 10.20	51.47 ± 11.10	
2 years	51.64 ± 9.95	50.87 ± 11.07	
3 years	50.99 ± 9.87	50.34 ± 11.26	
4 years	51.19 ± 10.22	50.10 ± 11.17	
5 years	50.83 ± 10.36	50.08 ± 10.52	0.52 (–0.58 to 1.63)

*CI = confidence interval, OKS = Oxford Knee Score, EQ-5D = EuroQoL 5D, and SF-12 = Short Form-12. †Values are given as the mean and the standard deviation. ‡Estimated with use of analysis of covariance, adjusting for minimization factors, baseline score, and surgeon. A positive score favors patellar resurfacing.

nonresurfacing groups for any of the individual levels of secondary procedures.

During the first five postoperative years, 0.8% of the patellar resurfacing group and 1.9% of the nonresurfacing group had late patellar resurfacing (odds ratio, 0.43; 95% CI, 0.16 to 1.16; p = 0.092). Patients in the patellar resurfacing group could undergo a late resurfacing if they did not receive the allocated resurfacing during the original operation. This was the case for 138 (16.0%) of the 861 patients allocated to receive resurfacing, and seven (5.1%) of these patients underwent a subsequent late resurfacing of the patella. Conversely, 759 of the 854 patients allocated to not receive resurfacing did not undergo a resurfacing during the primary operation, and sixteen (2.1%) of these patients underwent late patellar resurfacing. Two patients (both in the group allocated to resurfacing) who received a resurfacing subsequently underwent further surgery because of a patellar fracture.

In patients who received late patellar resurfacing, the mean OKS value deteriorated prior to the late resurfacing (Fig. 3). The mean OKS value (and standard deviation) was 15.3 ± 8.7 points the last time it was measured before the resurfacing and improved to 22.9 ± 9.6 points two years following the resurfacing, which was still considerably lower than the mean OKS value for the entire trial group.

Component costs were significantly higher in the patellar resurfacing group than in the nonresurfacing group (£1603

TABLE II Procedures Requiring Readmission Within Five Years

	Allocated to Patellar Resurfacing (N = 861)		Allocated to No Patellar Resurfacing (N = 854)				
	No.	%	No.	%	Odds Ratio	95% Confidence Interval	P Value
Total no. of procedures requiring readmission	167		202				
No. of patients requiring at least one readmission	104	12.1	112	13.1	0.91	0.67 to 1.23	0.54
Minor or intermediate operations							
Total no. of operations	57		83				
No. of participants requiring							
At least one minor or intermediate operation	38	4.4	50	5.8	0.74	0.44 to 1.25	0.27
Multiple minor or intermediate operations	12	1.4	16	1.9	0.74	0.32 to 1.68	0.42
No. of participants requiring at least one of							
Wound closure	3	0.3	5	0.6	0.59	0.09 to 3.6	0.071
Debridement or exploration/washout	15	1.7	24	2.8	0.62	0.31 to 1.23	0.17
Manipulation under anesthesia	18	2.1	23	2.7	0.77	0.41 to 1.43	0.40
Arthrolysis and quadricepsplasty	1	0.1	0	0.0			
Arthroscopy or examination under anesthesia/biopsy	5	0.6	8	0.9	0.62	0.20 to 1.95	0.42
Exchange of cement spacer	0	0.0	1	0.1			
Polyethylene exchange	3	0.3	5	0.6	0.59	0.09 to 3.6	0.72
Bone removal	2	0.2	0	0.0			
Patella-related operations							
Total no. of operations	9	1.0	16	1.9			
No. of participants requiring							
At least one patella-related operation	9	1.0	16	1.9	0.55	0.21 to 1.34	0.22
Multiple patella-related operations	0	0	0	0			
No. of participants requiring at least one of							
Patellar fracture treatment	2	0.2	0	0.0			
Late resurfacing	7	0.8	16	1.9	0.43	0.16 to 1.16	0.09
Major operations							
Total no. of operations	15		29				
No. of participants requiring							
At least one major operation	14	1.6	25	2.9	0.56	0.29 to 1.06	0.076
Multiple major operations	1	0.1	4	0.5			
No. of participants requiring at least one of							
One-stage revision	9	1.0	11	1.3	0.83	0.37 to 1.89	0.657
Two-stage revision	6	0.7	14	1.6	0.42	0.13 to 1.17	0.11
Above-the-knee amputation	0	0.0	2	0.2			

compared with £1519 per patient; difference, £85; 95% CI, £56 to £113; $p < 0.001$; see Appendix). Readmissions and subsequent surgery accounted for 7.2% of the total cost in the patellar resurfacing group and 11.6% in the nonresurfacing group. The mean cost of readmission for major surgery (one-stage revision, two-stage revision, or above-the-knee amputation) was significantly lower in the resurfaced group (£218 per patient compared with £491; difference, –£274; 95% CI, –£525 to –£22; $p = 0.033$), although there was no significant difference in the mean cost of readmission involving minor surgery ($p = 0.070$) or patella-related surgery ($p = 0.193$). The mean cost of late patellar resurfacing, including the cost of the hospital stay, for the twenty-three patients who received this procedure was £3833 ± £1183.

The mean total health care cost did not differ significantly between the patellar resurfacing and nonresurfacing groups (£7577 compared with £7726 per patient; difference, –£149; 95% CI, –£574 to £277; $p = 0.494$) (see Appendix).

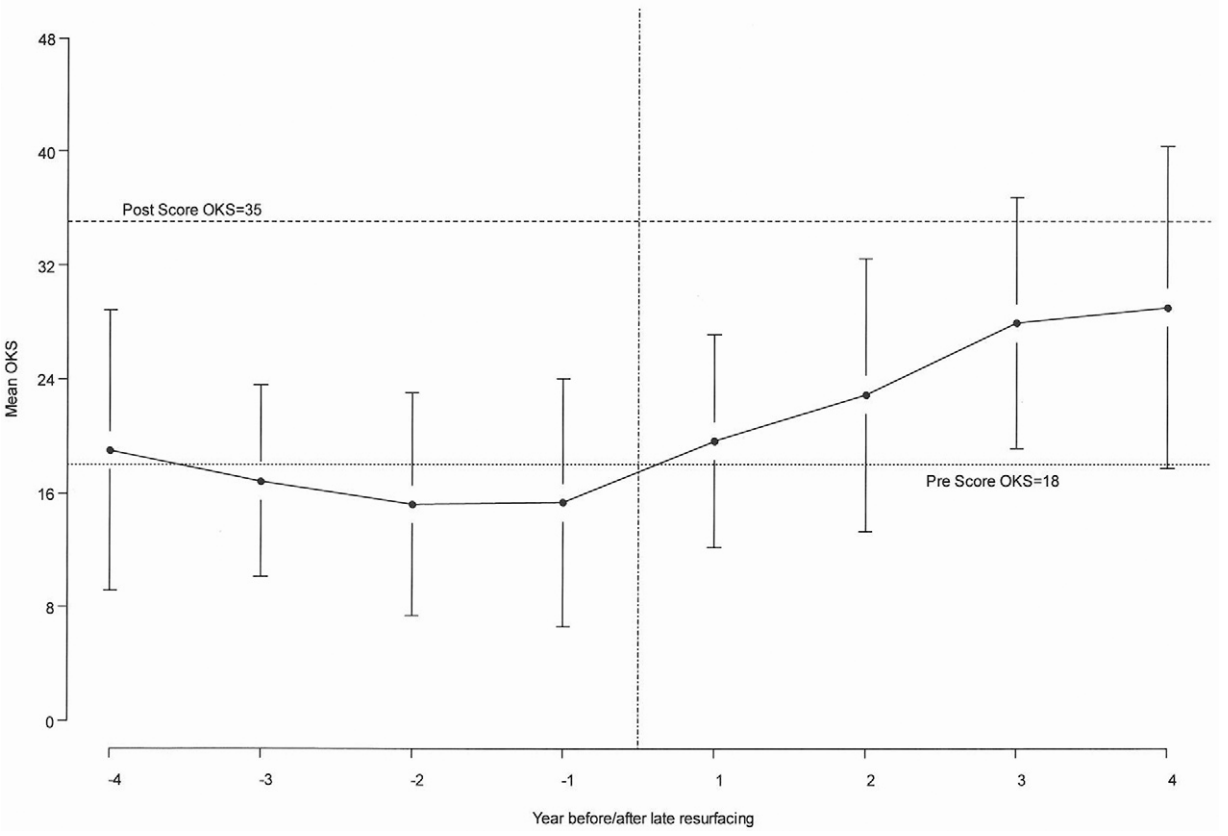

Fig. 3

The mean Oxford Knee Score (OKS) before and after resurfacing in the subgroup of patients who received late patellar resurfacing, compared with the mean postoperative score of all trial participants. The bars represent one standard deviation.

Discussion

The results of the current study indicate that patient functional status, patient quality of life, and total cost during the first five years after total knee arthroplasty are not significantly affected by the addition of patellar resurfacing to the initial surgical procedure. The 95% confidence interval for the difference in the OKS between the patellar resurfacing group and the nonresurfacing group was –0.6 to 1.8 at five years postoperatively. A clinically important difference on the OKS scale is believed to be approximately 3 points, and a 2-point difference is of possible clinical significance. This study was adequately powered to detect a clinically important difference, even taking into account the fact that some participants did not receive the allocated procedure. Similarly, there was no evidence of a clinically relevant difference in the EQ-5D or the SF-12.

Although the proportion of patients who underwent a patella-related reoperation was higher in the nonresurfacing group than in the patellar resurfacing group (2% compared with 1%), the difference was not statistically significant. The 2% rate of late resurfacing in the nonresurfacing group compares favorably with those in other published series of total knee arthroplasty in which the patella was not resurfaced[12]. The rate of late resurfacing was 5% in the subgroup of patients who were allocated to receive resurfacing during the initial operation but did not receive resurfacing at that time. The explanation for this observation is not obvious, but these patients may have been more likely to request resurfacing if they were aware that they had not received the expected patellar resurfacing previously, or their surgeons may have been more likely to advise them to have patellar resurfacing to treat any residual anterior knee pain. The results of this study suggest that a patient who receives a late resurfacing typically undergoes a gradual reduction in the knee functional score during the years prior to the resurfacing followed by an improvement after the resurfacing, but that the postoperative score does not reach the typical score reached by a patient following a first procedure. Patients to whom late resurfacing is recommended should be advised that this procedure is unlikely to provide complete relief of knee pain.

Although the proportion of patients undergoing a reoperation was higher in the nonresurfacing group than in the resurfacing group (5.8% compared with 4.4% for minor to intermediate reoperation and 2.9% compared with 1.6% for major reoperation), the differences were not statistically significant. It is striking that the rate of further surgery for almost every reason, and particularly for the treatment of an infection, was higher in the nonresurfacing group than in the resurfacing group. Nevertheless, we believe that these findings are probably due to random variations and do not indicate clinically important differences.

Patellar resurfacing significantly increased component costs for the primary operation by £85 (US$170 in 2007-2008)

and also increased the costs associated with operating room time and the length of the hospital stay, although the latter increases did not reach statistical significance. A more detailed cost breakdown that specifically accounted for the cost of the bone cement and sterilization of the instruments required for patellar resurfacing (rather than including the latter in the operating room overhead) might have resulted in a further slight increase in the incremental cost of resurfacing. However, the added cost incurred during the primary hospital stay was offset by a significant ($p = 0.033$) reduction in the cost associated with readmission for major surgery during the first five postoperative years. As a result, the economic analysis showed that the total health care cost during the first five years did not differ significantly between the groups. The price that National Health Service (NHS) hospitals in the U.K. pay for knee components is currently highly variable, and consequently the cost at a particular hospital may differ from the mean cost used in this analysis. However, varying the estimated discount between 0% and 50% of the manufacturer's list price did not alter our overall conclusions. A full economic evaluation is planned once all patients have been followed for eight years.

In conclusion, on the basis of five years of follow-up, there is no clear benefit to resurfacing the patella during total knee arthroplasty, as resurfacing had no significant effect on patient functional status, total treatment cost, or patient quality of life. Five years after the total knee arthroplasty, 2% of nonresurfaced patellae had required late resurfacing and 0.2% of resurfaced patellae had failed because of fracture. While the number of patellar failures may increase somewhat by ten years postoperatively, some surgeons may consider resurfacing the patella to be the preferred option because it is expected to offer a lower reoperation rate. Conversely, there should be no criticism of surgeons who elect not to resurface the patella during total knee arthroplasty, as the majority of patients will require no further patellar surgery.

Appendix

eA Tables showing patient-assessed outcomes and details of the economic analysis are available with the online version of this article as a data supplement at jbjs.org. ■

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